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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,502	12/17/2001	Kelly Moran	BJA219A	4304

7590 04/28/2005
BOLESH J. SKUTNIK PhD, JD
515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,502

Applicant(s)

MORAN, KELLY

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff (Pat. No. 4,287,554).

Wolff discloses that the electromagnetic radiation produced by his device may be employed to treat acne, psoriasis, or other skin related disorders. Wolff further discloses that wavelengths within the range from 193 nm to 10.6 micrometers are most effective in treating psoriasis, acne and other skin irregularities or diseases (col. 1, lines 49-57). It should be noted that applicant's claim 1 is drafted so broadly that it reads on someone with acne or an insect bite stepping outside into the sunlight, or simply turning on a reading lamp.

Regarding claim 12, the examiner considers the radiation produced by the Wolff device to be inherently capable of eradicating bacteria and viral bodies.

3. Claims 1, 2, 4, 6-8 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitehurst (Pat. No. 6,461,866).

Whitehurst discloses the use of a non-coherent, non-ablative light source useful in the cosmetic treatment of dermatological conditions such as portwine stains, psoriasis, etc. (col. 3, lines 32-46) with an output intensity of generally greater than 1 W/cm² (col. 1, lines 65-67), which can be focused and delivered via at least one optical

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fiber (col. 2, lines 4-7) at wavelengths in the range of 193 nm to 3 micrometers (col. 3, lines 47-53) and treatment times of 0-9999 seconds (col. 4, lines 29-36).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (Pat. No. 4,287,554).

Regarding claim 2, the examiner considers the power density of the Wolff device to be at least 1 W/cm² given the effects produced by the application of radiation energy. Since Wolff discloses that skin disorders such as acne and psoriasis may be effectively treated, the power density must be of a sufficient magnitude in order for any beneficial results to occur. Such a magnitude would necessarily be of a similar strength to the applicant's device since it also treats the same conditions by electromagnetic radiation of a similar wavelength. Concerning the exposure times, Wolff discloses that treatment times may correspond to the performance of mundane acts such as brushing ones teeth or combing one's hair. The examiner considers such acts to reasonably fall within the 1 second to 3 minute exposure time.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst.

While Whitehurst employs non-coherent light in the practice of his invention instead of coherent light (i.e., laser) due to the disadvantages listed in col. 1, lines 12-32 (e.g., high cost, size, power consumption, sophistication, etc.), it is well known in the art that coherent light may be used effectively despite its cost, size and complexity. Whether a system is more costly to purchase, takes up more space, or requires a higher skill level to operate does not negate the fact that such a system can be effective

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to treat skin disorders such as discussed by Whitehurst. By analogy, a diamond tipped jackhammer may be more costly to purchase and thus not recommended for use, yet such a tool would hardly be considered novel or unobvious given the known properties of diamonds. Likewise, given the known effectiveness of coherent light in treating dermatological disorders, those of ordinary skill in the art would have considered the use of a coherent light source such as a laser to be obvious for the healing of stage one and stage two wounds.

7. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst in view of Talmore (Pat. No. 5,344,433).

Whitehurst does not appear to explicitly discuss the average power of the radiation energy produced by the 300 W Xenon short arc lamp. Talmore, however, discloses the use of an identical light source and states that the lamp provides a light beam with an output of 1W (col. 4, lines 5-13). It would appear that the particular level of radiation power desired would depend upon the application at hand and the particular skin condition being treated. Lacking any criticality by the applicant in regards to providing a 1W output or a 5 to 10 W output, those of ordinary skill in the art would have seen the particular power level to be an obvious matter of design dependent upon the conditions of the particular wound being treated.

Response to Arguments

8. Applicant's arguments filed February 23, 2005 have been fully considered but they are not persuasive.

In the response to the rejection of claims 1, 8, 11 (now canceled) and 12 under Wolff '544, the applicant argues that while the apparatus of the '544 patent discloses medical uses such as the treatment of psoriasis, there is no suggestion to use the reference device together with optical fibers for medical purposes, and there is no suggestion that the reference device will prevent wound progression and enhance healing of stage 1 and stage 2 wounds. The examiner counters that nothing in claims 1, 8 or 12 require the use of optical fibers. Furthermore, the prevention of wound progression and enhancement of healing is simply a recitation of desired result in the claim preamble. Since the whole goal of wound treatment would be to prevent wound

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progression and enhance healing –not enhance wound progression and inhibit healing—it would be inherent that any ethical treatment method would attempt to prevent wound progression and enhance healing. In any event, Wolff explicitly teaches that the device may be used to treat psoriasis, eczema and even acne (listed by applicant to be exemplary of an early stage wound on page 5, lines 3-6 of the present specification).

The applicant further argues that the phrase “treatment of psoriasis” is a generic indication that does not teach the elements of the present invention with “sufficient specificity” as required by MPEP 2131. The applicant defines psoriasis as “...a common, scaly dermatosis characterized by red and raised patches of skin,” (page 3, lines 26-28). Furthermore, claim 1 does not specify that the stage 2 wound is an early stage 2 wound. As stated on page 1, lines 16-20, the prior art admittedly treats stage 2 wounds. Whether it is an early stage 2 wound or a late stage 2 wound is of no consequence since the claim does not differentiate between the two. In addition, a general teaching to treat psoriasis or eczema would necessarily include stage 1 and stage 2 wounds. A teaching to treat such skin disorders would automatically cover the treatment of differing severities of the same disorder. Nothing in the Wolff reference dictates one use the recited method only to treat wounds of a severe nature. Psoriasis is psoriasis regardless of the stage it is in.

Even if the applicant were to successfully argue the novelty rejection under Wolff, the examiner would consider it highly unlikely that such claims would be allowable given the general knowledge that medical treatments are most effective in the early stages, with the best chance of recovery directly correlated to the speed of diagnosis and the timeliness of treatment. The examiner further contends that the scope of claim 1 is so unduly broad, that it would read on a person with a mosquito bite stepping out into the sunlight since the sun can be considered a directed, non-ablative source of electromagnetic energy generating wavelengths within the recited range.

Regarding the rejection of claims 1-4 (claim 3 now canceled), 6-8, 11 (now canceled) and 12 under Whitehurst, the applicant argues that the removal of port wine stains and tattoos do not constitute wounds that require physical healing. The

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prevention of wound progression and enhancement of healing is considered to be a statement of desired result in the claim preamble. Whitehurst further teaches that one may treat psoriasis using the disclosed method. Psoriasis, according to the applicant's specification, is a wound requiring physical healing. Furthermore, the examiner considers it axiomatic that the treatment of psoriasis inherently involves the prevention of wound progression and enhancement of healing. One does not treat a wound with the intent of hastening its progression.

Concerning the rejection of claims 2-4 and 6 under §103 in view of '554, the applicant argues that there is no suggestion in the '554 reference for using electromagnetic radiation and optical fibers to stimulate the healing of stage 1 and stage 2 wounds. None of the claims listed above, however, require the use of optical fibers. Wolff clearly uses electromagnetic energy in the treatment of psoriasis, eczema and acne. As stated above, psoriasis is psoriasis regardless of the stage it is in. Even if *arguendo* the examiner were to agree with the applicant that the psoriasis (or eczema or acne) mentioned in the patent does not include stage 1 or stage 2 psoriasis, the examiner would consider the treatment of stage 1 or stage 2 psoriasis to be completely and blatantly obvious since it is an axiom in the medical field that the quicker a wound is treated, the more likely the wound will heal. Thus one would reasonably expect the method disclosed by the '554 reference to be successful in treating stage 1 and stage 2 wounds. In fact if anything, one would be more inclined to use the non-ablative method suggested by Wolff to treat minor wounds such as stage 1 and stage 2 than severe wounds with open sores given its operational wavelength and relatively low power. A device used for cosmetic purposes such as tanning would most likely not be expected to effectively treat open wounds and severe tissue, muscle or tendon damage. Ultraviolet radiation such as used for tanning, for example, has been known to treat mild cases of acne. To use directed, non-ablative electromagnetic radiation operating at one or more wavelengths in the recited range, as the '554 patent does, on an early stage of psoriasis to better one's chances for hastening the healing process, would have therefore in the very least been deemed obvious by those of ordinary skill in the art.

The arguments against allowance of claim 5 in view of Whitehurst '866 parallel those given above in the rejection of claims applied to this reference under §102.

Regarding the rejection of claims 9 and 10 under §103, the examiner disagrees with the applicant's conclusion that there would have been no reasonable expectation of success in preventing wound progression of stage 1 and 2 wounds. As stated above, the '866 patent discloses that psoriasis and skin disorders may be treated with the non-ablative electromagnetic radiation source. The '866 patent discloses operating parameters in the general range recited by the applicant. The '433 patent discloses that electromagnetic radiation sources of the type disclosed by Whitehurst may emit an average power of a similar magnitude to that claimed in the present application. Because the particular level of average power would depend on the application at hand, routine experimentation would have been seen as the most obvious path to take in order to establish the most effective levels for treating psoriasis.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

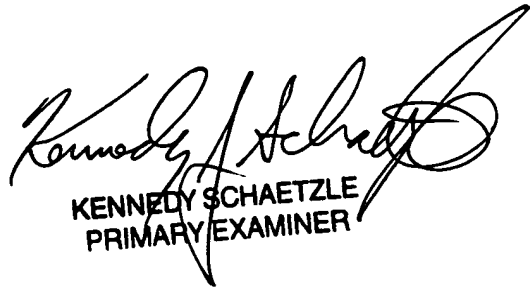
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 25, 2005



KENNEDY SCHAETZLE
PRIMARY EXAMINER